2022-1363

United States Court of Appeals for the Federal Circuit

UNITED CANNABIS CORPORATION,

Plaintiff-Appellee,

– v. –

PURE HEMP COLLECTIVE INC.,

Defendant-Appellant.

On Appeal from the United States District Court for the District of Colorado in No. 1:18-cv-01922-WJM-NYW Honorable William J. Martinez, Judge

BRIEF FOR DEFENDANT-APPELLANT

JAMES R. GOURLEY
CARSTENS & CAHOON, LLP
1707 Cole Boulevard, Suite 210
Denver, Colorado 80401
(720) 798-6620

Counsel for Defendant-Appellant

MARCH 14, 2022

REPRESENTATIVE PATENT CLAIMS

U.S. Patent No. 9,730,911 (the '911 Patent)

10. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is cannabidiol (CBD).

20. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids are THC and CBD.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1363

Short Case Caption United Cannabis Corporation v. Pure Hemp Collective Inc.

Filing Party/Entity Pure Hemp Collective Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 01/27/2022

Signature: /s/ James R. Gourley

Name: James R. Gourley

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Pure Hemp Collective Inc.		

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Donald Emmi		

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes & Other Authorities:

TABLE OF ABBREVIATIONS

'911 Patent	U.S. Patent No. 9,730,911 (the patent-in-suit)
CBD	Cannabidiol
IDS	Information Disclosure Statement
THC	Delta-9 Tetrahydrocannabinol
USPTO	U.S. Patent and Trademark Office

STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 47.5, Pure Hemp states as follows:

(a) No previous appeal has been taken in this action.

(b) No other case pending in this or any other court or agency will directly affect or be directly affected by this court's decision in the pending appeal.

STATEMENT OF JURISDICTION

The parties stipulated that United Cannabis's patent infringement claims against Pure Hemp were dismissed with prejudice in the District of Colorado. This Court held in *Keith Mfg. Co. v. Butterfield* that a dismissal with prejudice is a final order that allows the prevailing party to file a motion for attorney's fees.[1] The district court denied Pure Hemp's timely post-judgment motion for attorney's fees and sanctions on December 22, 2022. Pure Hemp timely filed a Notice of Appeal on January 10, 2022. This Court has jurisdiction over all appeals from patent infringement cases under 28 U.S.C. Sections 1292 and 1295.

[1] *Keith Mfg. Co. v. Butterfield*, 955 F.3d 936, 940 (Fed. Cir. 2020).

I. STATEMENT OF THE ISSUES

(1) United Cannabis dismissed its patent infringement claims *with prejudice*, while Pure Hemp dismissed its counterclaims *without prejudice*. The stipulated dismissal was silent on attorney's fees. Was it an abuse of discretion for the district court to find that Pure Hemp was not the prevailing party in this case under 35 U.S.C. Section 285?

(2) In support of its motion for attorney's fees and sanctions, Pure Hemp presented:

- evidence of inequitable conduct on the part of the law firm that both procured the patent-in-suit for United Cannabis and represented United Cannabis in this litigation, and
- undisputed evidence that the same law firm took inconsistent positions on behalf of United Cannabis and a different, unrelated client regarding which of those clients invented the formulation claims at issue.

Did the district court abuse its discretion by failing to conduct an adequate inquiry into these factors because they "involved factual disputes" that had not been "adjudicated on the merits" before the case was dismissed?

(3) The attorney who prosecuted the patent-in-suit admitted to copying and pasting text from the prior art into the patent specification and not disclosing that prior art to the USPTO. During the litigation, the same law firm took inconsistent positions before the district court and the USPTO on a critical issue: which of its clients–United Cannabis or a different, unrelated client–invented 95% pure CBD in

a liquid formulation. Do these factors make this not only an exceptional case, but one that calls for the law firm to be sanctioned as well?

II. STATEMENT OF THE CASE

Pure Hemp prevailed in this case by securing dismissal of United Cannabis's claims with prejudice, but only after litigating it for years in the district court and through United Cannabis's failed attempt at federal bankruptcy protection. The win was unequivocal. Pure Hemp will never be burdened with litigation over the '911 Patent ever again but is free to revive its claims against United Cannabis should it choose to do so. After it secured this victory, Pure Hemp asked the district court to not only award its attorney's fees under 35 U.S.C. Section 285, but also sanction the law firm representing United Cannabis: Cooley LLP.

This extraordinary request stemmed mainly from three extraordinary circumstances, all involving Cooley:

First, the Cooley attorney who drafted and prosecuted the '911 Patent admitted to copying and pasting significant amounts of text from a material prior art reference into the '911 Patent specification and admitted that she did not disclose that reference to the USPTO. That prior art reference was owned by a company called GW Pharma.

Second, in the middle of this district court litigation, Cooley began representing GW Pharma in patent prosecution before the USPTO. During that representation, Cooley attorneys filed claim sets with the USPTO that cover one of the '911 Patent claims asserted in this litigation: 95% pure CBD in a liquid

formulation. Moreover, the GW Pharma patent applications Cooley was prosecuting during this litigation had an earlier priority date than the '911 Patent. So Cooley's position as to GW Pharma at the USPTO was more credible than its position as to United Cannabis at the district court. And Cooley's position as to GW Pharma, if correct, would materially and adversely affect United Cannabis.

Third, Cooley funded this baseless litigation against Pure Hemp. When United Cannabis filed for federal bankruptcy protection, Cooley filed a claim in that proceeding for more than $1,000,000.00 in unpaid legal fees and more than $50,000.00 in unpaid costs.[2]

In sum, Cooley's improper actions led to the genesis of this lawsuit, and Cooley facilitated its continuation long after its attorneys could hold a good faith belief in the merits of the case by taking inconsistent positions at different tribunals on behalf of different clients and by financing this case for more than a year. Pure Hemp was forced to incur $298,567.50 in attorney's fees.[3] Although United Cannabis was also at fault, Cooley was most responsible for the injuries suffered here. These facts are described in detail below.

[2] Appx456-458
[3] Appx226-234

A. Cooley obtained the '911 Patent for United Cannabis.

Cynthia Kozakiewicz, an attorney at Cooley, drafted and prosecuted the patent application that issued as U.S. 9,730,911 (the '911 Patent).[4] It was filed in 2014 and issued in 2017 with claims directed to liquid cannabinoid formulations.[5] Claim 10 requires that at least 95% of the total cannabinoids is CBD, while claim 20 requires that at least 95% of the total cannabinoids are CBD and THC.[6] United Cannabis accused Pure Hemp of infringing both claims.

Kozakiewicz admitted during her deposition that she copied and pasted text from a prior art reference ("Whittle" – U.S. Pat. Pub. No. 2004/0033280) into the Abstract and Detailed Description sections of the '911 Patent.[7] Some of the language copied from Whittle related to liquid formulations, including that "[p]referred dosage forms include … liquid dosage forms" and that "[s]uch dosage forms may be prepared in accordance with standard principles of pharmaceutical formulation, known to those skilled in the art."[8] Kozakiewicz also copied from Whittle regarding "methods of calculating cannabinoid content (as %)" and from the Wikipedia page on cannabinoids into the '911 Patent.[9] Kozakiewicz also admitted

[4] Appx16
[5] *Id*.
[6] Appx25-26
[7] Appx277; Appx281-282
[8] *Compare* Appx397 at para. [0099]) *with* Appx361 at col. 7, ll. 51-62.
[9] *Compare* Appx396 at para. [0070] *with* Appx361 at col. 7, ll. 6-8; *compare* Appx411-412 *with* Appx360 at col. 5, l. 20 to col. 6, l. 11.

that she never disclosed Whittle to the USPTO during prosecution of the '911 Patent.[10]

B. Whittle discloses cannabis extracts with high levels of CBD and THC, and liquid cannabinoid formulations including them.

Whittle discloses a cannabis extract obtained from a "cannabis plant having a CBD content of at least 90% w/w of total cannabinoid content" that "comprises at least 50% CBD w/w of extract, no more than 7.5% THC w/w of the CBD content, and no more than 5% cannabinoids other than CBD and THC expressed as % w/w of the CBD content."[11] Using simple math, the disclosed ranges for CBD and CBD+THC in the extract can be recalculated on the basis of total cannabinoids.[12] As recalculated, Whittle discloses a cannabis extract with:

- at least 88.9% CBD on the basis of total cannabinoids; and
- at least 95.6% CBD+THC, and no more than 4.4% cannabinoids other than CBD and THC.

Although the range of CBD in the Whittle extract is not identical to claim 10 of the '911 Patent, it fully encompasses and is very close to claim 10. Whittle's range for CBD+THC is almost identical to the range of claim 20 of the '911 Patent. To be clear, Whittle's disclosure that cannabinoids other than CBD and THC be no

[10] Appx282
[11] Appx396
[12] Appx215

more than 4.4% of the total cannabinoids requires that CBD+THC is at least 95.6% of the total cannabinoids in this extract.

Additionally, Whittle discloses a prior art method that produces "high CBD extract containing" 60% CBD, 4% THC, and 2% other cannabinoids.[13] When recalculated as a percentage of total cannabinoids using simple math, this Whittle disclosure describes a high CBD extract wherein 97% of total cannabinoids are THC and CBD.

Thus, Kozakiewicz copied and pasted from Whittle, which was material to patentability for at least claims 10 and 20 of the '911 Patent because it:

- discloses liquid cannabinoid formulations (also describing liquid formulations as "preferred") with a range of CBD that is very close to and fully encompasses claim 10,
- a range of CBD+THC that is almost identical to and falls completely within the range of claim 20, and
- a species of prior art that is within the range of claim 20.

C. Kozakiewicz intentionally withheld Whittle from the USPTO.

Kozakiewicz also stated during her deposition that Cooley has a policy of withholding references from the USPTO until a first office action is received.[14] This

[13] Appx393 at paras. [0013], [0019]-[0022].
[14] Appx213 at para. 16; Appx244 at ll. 17-24.

policy differs from the Manual of Patent Examination Procedure (MPEP), which states: "An applicant, attorney, or agent who is aware of material prior art or other information and its significance should submit the information early in prosecution, e.g., before the first Office action."[15] Contrary to both Cooley's policy and the MPEP, Kozakiewicz never submitted Whittle to the USPTO.

D. During this litigation, Cooley started representing GW Pharma – the owner of Whittle.

In 2019, attorneys at Cooley began representing GW Pharma (the owner of Whittle[16]) in patent prosecution at the USPTO. In three separate pending patent applications, Cooley attorneys told the USPTO that GW Pharma invented liquid formulations that include CBD at a purity of at least 95%, and methods of using them.[17] For example, Cooley attorneys acting for GW Pharma submitted this claim to the USPTO:

[15] Manual of Patent Examination Procedure. Section 2003. Ninth Edition, Revision 10.2019, Last Revised June 2020.
[16] *See* Appx552; U.S. Pat. No. 7,344,736 (claiming priority to Whittle and listing GW Pharma Limited as owner)
[17] U.S. Patent Application Serial No. 16/570,220; Appx432; Appx429; U.S. Pat. App. Ser. No. 16/198,141; Appx448-452; Appx455; U.S. Pat. App. Ser. No. 16/678,961; Appx441-444; Appx446; Appx216-218 at para. 28-38

> 20. (Currently amended) An oral composition comprising:
> (i) CBD at a concentration of between about 90 mg/ml and about 110 mg/ml, wherein the CBD has a purity of at least about 95% (w/w);
> (ii) ethanol at a concentration of about 71.1 mg/ml to about 86.9 mg/mL;
> (iii) a sweetener at a concentration of about 0.45 mg/ml to about 0.55 mg/ml;
> (iv) ~~flavouring~~ flavoring at a concentration of about 0.18 mg/ml to about 0.22 mg/ml; and
> ([[ii]]v) sesame oil, q.s. to about 1.0 ml.

An oral composition containing CBD at a purity of at least about 95% that is dissolved in ethanol, a sweetener, a flavoring, and sesame oil is a liquid cannabinoid formulation that reads identically on claim 10 of the '911 Patent. GW Pharma's formulation is more specific in its ingredients, but ethanol is a liquid, sesame oil is a liquid, and a composition made according to this claim could be accused of infringing claim 10 of the '911 Patent.

Also, the applications Cooley was prosecuting at the USPTO on behalf of GW Pharma had an earlier priority date than the '911 Patent.[18] The '911 Patent has an earliest priority date of October 21, 2014.[19] The GW Pharma patent applications claimed priority to a British patent application filed on October 14, 2014.[20]

[18] Appx216 at para. 28-29; Appx570
[19] Appx16
[20] Appx570

E. The parties stipulated that all claims asserted by United Cannabis were dismissed with prejudice, while Pure Hemp's counterclaims were dismissed without prejudice. Pure Hemp then filed its motion for attorney's fees and sanctions.

After the bankruptcy petition United Cannabis had filed in the District of Colorado Bankruptcy Court was dismissed, the parties stipulated to dismissal of this case. In the stipulation of dismissal, all of the claims asserted by United Cannabis were dismissed with prejudice, and Pure Hemp's counterclaims were dismissed without prejudice.[21] The stipulation was silent as to costs and attorney's fees. Pure Hemp then timely filed its motion for fees and sanctions based in large part on the facts described above.[22]

F. The district court denied Pure Hemp's motion for attorney's fees and sanctions because, in the court's opinion, Pure Hemp was not the prevailing party, there were still factual disputes, and the issues raised had not been decided on the merits.

On December 22, 2021, the district court denied Pure Hemp's motion for attorney's fees and sanctions.[23] After summarizing the legal standard and stating that it had fully considered the parties' arguments, the court offered a single paragraph of analysis, with a footnote:

> Ultimately, the Court finds that Defendant has failed to establish that it is the prevailing party under section 285, that this is an 'exceptional' case warranting an attorney's fee award, or that Plaintiff's counsel has

---

[21] Appx190-192

[22] Appx194

[23] *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, Civil Action No. 18-cv-1922-WJM-NYW, 2021 U.S. Dist. LEXIS 243849, at *3 (D. Colo. Dec. 22, 2021).

> acted in a vexatious or otherwise unreasonable manner. In making this determination, the Court notes that the parties stipulated to dismissal of this case before many of the factual disputes Defendant cites were adjudicated on the merits. (ECF No. 91.) The record on the substantive merits and the materiality of Plaintiff's purportedly inequitable conduct is woefully undeveloped, and as such, does not paint a persuasive picture for awarding fees.[1]
>
> [1] Moreover, Defendant's arguments regarding the strength of its litigating position are belied by the fact that the Court denied Defendant's Early Motion for Partial Summary Judgment.

The impropriety of the district court's scant analysis of the facts, including the complete lack of context around its footnote, is discussed in detail in the arguments section below.

III. SUMMARY OF ARGUMENT

Pure Hemp prevailed in this action when United Cannabis dismissed its claims with prejudice. This Court held in *B.E. Tech., L.L.C. v. Facebook, Inc.*[24] and *Raniere v. Microsoft Corp.*[25] that a decision on the merits is not required for a party to prevail. Instead, a defendant must simply rebuff the plaintiff's claims or receive all of the relief it was entitled to. Pure Hemp achieved a complete win: dismissal with prejudice. The district court abused its discretion by finding that Pure Hemp was not the prevailing party.

The district court also abused its discretion by refusing the wade into the alleged "factual disputes" and unresolved merits questions in denying Pure Hemp's motion for fees and sanctions. When this Court has affirmed an inequitable conduct finding based on the patentee copying from the prior art without disclosing that art to the USPTO[26], and when the District of Colorado has found the same[27], the district court could not simply dismiss undisputed evidence that the same thing happened here. The only possible dispute in this case involves whether the failure to disclose was done with specific intent to deceive, and the district court refused to wade into

[24] *B.E. Tech., L.L.C. v. Facebook, Inc.*, 940 F.3d 675, 678 (Fed. Cir. 2019).
[25] *Raniere v. Microsoft Corp.*, 887 F.3d 1298 (Fed. Cir. 2018)
[26] *Am. Calcar v. Am. Honda Motor Co.*, No. 06-cv-2433 DMS (KSC), 2012 U.S. Dist. LEXIS 54059, at *10 (S.D. Cal. Apr. 17, 2012) *aff'd*, 768 F.3d 1185, 1192 (Fed. Cir. 2014).
[27] *CCC Grp., Inc. v. Martin Eng'g Co.*, 683 F. Supp. 2d 1201, 1209 (D. Colo. 2010).

that question. The same is true of the undisputed evidence that Cooley attorneys took a position on behalf of one client before the USPTO that, if true, would be damaging to United Cannabis in the district court litigation.

When this Court considers all of the evidence, it can not only reverse the district court's findings, it can also affirmatively hold that this case was exceptional, that fees and sanctions are appropriate, and remand the case for determination of the appropriate fee award.

IV. ARGUMENT

A. LEGAL STANDARDS

This Court applies "an abuse-of-discretion standard in reviewing all aspects of a district court's §285 determination."[28] An abuse of discretion occurs where a district court makes "a clear error of judgment in weighing relevant factors or in basing its decision on an error of law or on clearly erroneous factual findings."[29] "A factual finding is clearly erroneous if, despite some supporting evidence," the Court is "left with the definite and firm conviction that a mistake has been made."[30]

A court may award reasonable attorney fees to the prevailing party in a patent

---

[28] *Highmark Inc. v. Allcare Health Mgmt. Sys.*, 572 U.S. 559, 564, 134 S. Ct. 1744, 1749 (2014).
[29] *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302, 1306 (Fed. Cir. 2017) (internal quotation marks and citation omitted).
[30] *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 858 (Fed. Cir. 2015) (internal quotation marks and citation omitted)

infringement case.[31] In *B.E. Tech., L.L.C. v. Facebook, Inc.*, this Court held that a decision on the merits "is not a prerequisite to a finding of prevailing party status" under Fed. R. Civ. P. 54.[32] In doing so, this Court relied on an analogous Supreme Court case and cited to *Raniere v. Microsoft Corp.* as applying the same interpretation to "prevailing party" under Section 285.[33] Instead of looking solely at the merits, a court should determine whether a court order in favor of a defendant "effects or rebuffs a plaintiff's attempt to effect a 'material alteration in the legal relationship between the parties'" or whether the defendant "received all relief to which they were entitled."[34] In *Keith Mfg. Co. v. Butterfield*, this Court held that a stipulated dismissal *with prejudice* under Rule 41(a) is a judgment under Rule 54 that allows the prevailing party to file a motion for fees, and noted that the Tenth Circuit reached a similar conclusion.[35]

"[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the

---

[31] 35 U.S.C. 285.
[32] *B.E. Tech.*, 940 F.3d at 678.
[33] *Id*. at 679 (citing *CRST Van Expedited, Inc. v. E.E.O.C.*, 136 S. Ct. 1642, 194 L. Ed. 2d 707 (2016); *Raniere*, 887 F.3d at 1298.
[34] *Id*. (quoting *CRST*, 136 S. Ct. at 1651).
[35] *Keith Mfg.*, 955 F.3d at 940 (citing *Xlear, Inc. v. Focus Nutrition, LLC*, 893 F.3d 1227, 1235-36 (10th Cir. 2018)).

case was litigated."[36] Exceptionality is evaluated "case-by-case . . . considering the totality of the circumstances."[37]

In *AdjustaCam, LLC v. Newegg, Inc.*, this Court reversed the district court and held that although a "district court need not reveal its assessment of every consideration of" Section 285 motions, "it must actually assess the totality of the circumstances."[38] Accordingly, a district court abuses its discretion when it "fail[s] to conduct an adequate inquiry" into the totality of the circumstances.[39]

An attorney "who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct."[40] Costs and fees may be awarded under § 1927 "when an attorney is cavalier or bent on misleading the court; intentionally acts without a plausible basis; [or] when the entire course of the proceedings was unwarranted."[41] An award also requires findings that the attorney's conduct was improper and unreasonably multiplied the proceedings.[42]

---

[36] *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554, (2014).
[37] *Id*.
[38] *AdjustaCam, LLC v. Newegg, Inc.*, 861 F.3d 1353, 1360 (Fed. Cir. 2017).
[39] *Rothschild Connected Devices Innovations, LLC v. Guardian Prot. Servs.*, 858 F.3d 1383, 1388 (Fed. Cir. 2017) (*citing Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1360 (Fed. Cir. 2011)).
[40] 28 U.S.C. § 1927.
[41] *Dominion Video Satellite, Inc. v. Echostar Satellite L.L.C.*, 430 F.3d 1269, 1278 (10th Cir. 2005)
[42] *See Braley v. Campbell*, 832 F.2d 1504, 1509, 1513 (10th Cir. 1987).

In the District of Colorado, when multiple firm lawyers and staff are involved, liability "should be borne by the firm" under either Section 1927 or the court's inherent authority, which also allows a court to impose a fee award against counsel for bad faith.[43]

B. Pure Hemp was the prevailing party at the district court because United Cannabis dismissed its claims with prejudice, while Pure Hemp dismissed its claims without prejudice.

The district court did not even cite *B.E. Tech.* in its opinion. But it should have, because under this Court's precedent in *B.E. Tech.* and the cases cited therein, Pure Hemp was successful in rebutting United Cannabis's attempt to effect a material alteration in the legal relationship between the parties.[44] Pure Hemp also obtained all of the relief to which it was entitled on the United Cannabis patent infringement claims: dismissal with prejudice. Pure Hemp is therefore the prevailing party.

In its response brief before the district court, United Cannabis did not dispute that Pure Hemp was the prevailing party. In its introduction, United Cannabis did allege that it "prevailed at every stage of this litigation" before it dismissed its claims with prejudice.[45] That allegation is not correct, but even if it were true, ultimately

---

[43] *Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersystems GmbH*, Civil Action No. 98-cv-01072-RPM, 2008 U.S. Dist. LEXIS 13483, at *33-34 (D. Colo. Feb. 12, 2008)
[44] *See B.E. Tech.*, 940 F.3d at 679.
[45] Appx576

this litigation was a total loss for United Cannabis, and Pure Hemp will never again suffer the burden of litigating over the 911 Patent.

C. The district court failed to conduct an adequate inquiry into the totality of the circumstances in denying Pure Hemp's motion for attorney's fees.

After the district court stated that it considered all of the parties' arguments, it cited the following three reasons (all in the single paragraph of analysis) for denying Pure Hemp's motion[46]:

1. The "parties stipulated to dismissal of this case before many of the factual disputes Defendant cites were adjudicated on the merits";
2. The "record on the substantive merits and the materiality of Plaintiff's purportedly inequitable conduct is woefully undeveloped"; and
3. "Defendant's arguments regarding the strength of its litigating position are belied by the fact that the Court denied Defendant's Early Motion for Partial Summary Judgment."

Reasons 1 and 2 above plainly reveal that the Court did not conduct an adequate inquiry into the totality of the circumstances in this case. There is no requirement or even suggestion in this Court's precedent that every factual dispute or merits question must be finally resolved before a fee motion can be filed. Indeed, the motion for fees asked that the Court look into these supposed factual disputes and merits-based arguments, and determine whether the preponderance of the evidence presented shows that this is an exceptional case. By citing factual disputes

[46] Appx2-3

and unadjudicated merits questions as reasons for denial of fees, the court demonstrated that it did not wade into them at all.

Reason 3 is more concrete than reasons 1 and 2 in that reason 3 refers to an actual event in the case. But the district court did not conduct a reasonable inquiry into the totality of the circumstances surrounding that summary judgment motion either. The simple fact that Pure Hemp's early summary judgment motion on the issue of patent eligibility under Section 101 was denied obscures two important aspects of that ruling:

First, even though novelty and obviousness were not raised in Pure Hemp's motion, the district court went out of its way to provide the following early assessment of the substantive merits: "To be clear, the Court sees reason to question whether the 911 Patent claims anything novel, useful, or nonobvious."[47] This sobering assessment should have been taken seriously by United Cannabis because at the time of this ruling it knew the motion papers did not discuss the closest prior art, including Whittle – the GW Pharma reference that the prosecuting attorney had copied and pasted from while drafting the 911 Patent specification.

Second, in response to Pure Hemp's summary judgment motion, United Cannabis took the extraordinary steps of disclaiming several of its patent claims,[48]

[47] Appx145
[48] Appx146

and after the court denied its request for judicial correction of claim 31[49], seeking a Certificate of Correction from the USPTO[50] to correct problems Pure Hemp identified in the summary judgment motion. These steps should have been taken before United Cannabis filed suit, and Pure Hemp would have prevailed on those aspects of its motion had United Cannabis not taken the actions it did, including surrendering rights by disclaiming patent claims.

So although the district court's statement is true – Pure Hemp's early summary judgment motion was denied – that opinion gave the parties a crucial early read on the substantive merits and would have come out differently had United Cannabis not dedicated a portion of its intellectual property rights to the public domain and sought a Certificate of Correction from the USPTO.

D. Had the district court conducted an adequate inquiry, it would have found that this case was extraordinary and that sanctions were warranted.

Pure Hemp presented two main circumstances that should have caused any reasonable inquiry into the totality of the case to conclude not only that this case was exceptional, but that the law firm should be sanctioned for its role. The district court was incorrect in finding that the factual record in this case was undeveloped. The parties engaged in years of litigation, and United Cannabis filed for bankruptcy

[49] Appx69-78
[50] Appx159-161

protection shortly before expert reports were due. The discovery process yielded many important facts, which were described above and are analyzed below.

First, there is no factual dispute that the Cooley attorney who drafted and prosecuted the 911 Patent admitted under oath during a deposition to copying and pasting from a prior art reference into the patent specification and not disclosing that reference to the USPTO. At least two district courts (including the District of Colorado) have rightly held that such conduct is deceptive and inequitable.[51] One of those decisions was upheld on appeal by this Court. United Cannabis has cited to no authority excusing such behavior. The bottom line is that copying and pasting from the prior art into a patent specification and not disclosing that prior art to the USPTO should raise a *prima facie* concern that the reference was relevant to patentability, should demand close inspection of the facts surrounding it, and cannot be dismissed in three sentences of generic analysis.

Second, there is no factual dispute that during the district court litigation, the same law firm started representing GW Pharma in patent prosecution at the USPTO. GW Pharma owns Whittle, the reference that a Cooley attorney copied from and failed to disclose. During its representation of GW Pharma, Cooley attorneys told the USPTO several times that GW Pharma invented formulations that include each

[51] *CCC Grp.*, 683 F. Supp. 2d at 1209; *Am. Calcar*, 2012 U.S. Dist. LEXIS 54059, at *10 (S.D. Cal. Apr. 17, 2012) *aff'd*, 768 F.3d 1185, 1192 (Fed. Cir. 2014).

and every element of claim 10 of the 911 Patent. Cooley's position as to GW Pharma was more credible than its position as to United Cannabis because GW Pharma has an earlier priority date. Again, these factual allegations were detailed in Pure Hemp's motion, and United Cannabis did not dispute them. United Cannabis's only defense consisted solely of procedural theories about why the district court should not consider Cooley's representation of GW Pharma in deciding the motion[52], none of which were meritorious. Both of these circumstances are discussed in more detail below.

i. United Cannabis's counsel committed inequitable conduct by copying and pasting text from Whittle into the 911 Patent, but intentionally withholding it from the USPTO during prosecution of the 911 Patent.

Although it is unclear post-*Octane* whether a defendant must prove inequitable conduct under the "clear and convincing" or "preponderance of the evidence" standard in a Section 285 motion[53], Cooley's actions in this case satisfy either one. In *CCC Group*, the District of Colorado held that "selective use of a single illustration from [a prior art book], without identifying the source or providing the book to the Examiner, was contrary to the duty of candor."[54] Another district court case involving analogous facts found that several "drawings in the patent

[52] Appx585-586
[53] *See*, *e.g.*, *Degussa v. Materia, Inc.*, 305 F. Supp. 3d 563, 569 (D. Del. 2018)
[54] *CCC Grp.*, 683 F. Supp. 2d at 1209.

application are identical, in all relevant respects, to figures in" a car navigation system manual that was material to patentability but withheld from the USPTO during prosecution with intent to deceive.[55] That finding was upheld on appeal by this Court.[56]

During the prosecuting attorney's deposition, she stated several times that she only recalled seeing those portions of Whittle that were copied into the 911 Patent, and that she did not deem those sections material to patentability.[57] In *CCC Group*, Judge Matsch in the District of Colorado confronted almost identical testimony and found it to lack credibility, stating:

> Bradbury testified that he had not read the entire [prior art book] and was unaware of its teachings. That testimony is not credible. Bradbury obviously knew enough about [the book] to use it to illustrate prior art. He must have known that [the book] addressed chute design and the advantages of spacious enclosures.[58]

In the instant case, the facts are even more troublesome because there is no credible dispute that the Cooley attorney was aware of the sections she copied

---

[55] *Am. Calcar*, 2012 U.S. Dist. LEXIS 54059, at *10.
[56] *See Am. Calcar*, 768 F.3d at 1192; *cf*, *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1335-36 (Fed. Cir. 2012)(partial disclosure of material information about the prior art to the PTO cannot absolve a patentee of intent if the disclosure is intentionally selective.); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1376 (Fed. Cir. 2000) (finding intent where the patentee disclosed a complete reference in Japanese but did not provide translations of that part which was material to patentability)
[57] Appx282 at ll. 21-24; Appx283 at ll. 1-11; Appx284 at ll. 5-12; Appx298 at ll. 5-20
[58] *CCC Grp.*, 683 F. Supp. 2d at 1209.

regarding liquid cannabinoid formulations, and the 911 Patent claims related directly to liquid cannabinoid formulations.

Finally, at a fundamental level, the act of copying and pasting without citing to the source is widely recognized as deceptive. In academic circles, it is referred to as plagiarism. The single most reasonable inference based on all of the actions during prosecution of the 911 Patent is that Whittle was withheld from the USPTO with intent to deceive.

The only possible reason there could be a factual dispute regarding inequitable conduct is because the prosecuting attorney did not admit that she withheld the reference with specific intent to deceive. That is the only possible factual dispute that was not resolved at the district court before the case was dismissed. But the court had an opportunity to consider the exact same evidence of deceptive intent in the context of Pure Hemp's fee motion, and it failed to do so.

ii. United Cannabis did not cite a single authority that would excuse this behavior.

The only two sources cited by United Cannabis in support of its position do not endorse copying and pasting without citing the source to the USPTO. The first[59] is the 2008 version of David Pressman's book *Patent It Yourself* – a guide intended to help nonlawyers draft and prosecute their own patent applications.[60] Assuming

[59] *See* Appx587 at fn. 2.
[60] David Pressman, *Patent It Yourself*, (13th ed. 2008).

for purposes of argument that a professionally trained and experienced patent lawyer would take advice from such a book, that lawyer would be advised time and again by Pressman that material prior art must be disclosed to the patent office.[61] Moreover, although the 2008 version of Pressman's book rhetorically endorsed plagiarism, later versions dropped the language about plagiarism and provided advice on copying that was more circumspect. Pressman now advises that "you can copy the ideas in prior art materials if you express those ideas in your own words, instead of simply copying text and figures."[62]

The other source cited by United Cannabis[63] is a blog post by Gene Quinn that also cites Pressman (2008) for the same proposition.[64] However, there is no indication in the Quinn blog post that the copy-and-paste source being discussed was not disclosed to the UPSTO. Further, according to Quinn, John White stated that generally copying is done with explicit attribution, though he says there is no requirement to do so. But John White never says anything about whether lack of disclosure to the USPTO is appropriate when material is copied and pasted from the prior art.

---

[61] *Id*. at p. 14, 148, 180, 195, 252, 271, 280, 284, 330, 332, 335 and 415; Appx792-806.
[62] David Pressman, *Patent It Yourself*, (20th ed. 2020); Appx808.
[63] *See* Appx587 at fn. 2.
[64] Gene Quinn, *Ropes & Gray Seeks Dismissal of Patent Malpractice Lawsuit*, IPWATCHDOG (Mar. 28, 2010)

Neither source cited by United Cannabis is authoritative, and neither supports the proposition that a patent lawyer may copy and paste from the prior art without disclosing that reference to the USPTO. The lack of disclosure is the problem here – not the copying and pasting by itself.

iii. United Cannabis's counsel took different positions in different tribunals on behalf of different clients on which one invented liquid cannabinoid formulations that include at least 95% pure CBD.

The GW Pharma patent applications on liquid formulations with 95% pure CBD that Cooley was prosecuting claim priority to a British patent application filed on October 14, 2014 – one week before the earliest priority date of the 911 Patent.[65] The GW Pharma claims are more detailed but read exactly on the 911 Patent claims, because as this Court held in *Upsher-Smith Labs. v. Pamlab, L.L.C.*, that which would infringe if later in time anticipates if earlier.[66] Cooley's position as to GW Parma being the inventor is more credible than its position as to United Cannabis because of GW Pharma's earlier priority date.

Cooley's actions directly implicate ABA Model Rule 1.7 regarding conflicts of interest between current clients. Comment 24 to Rule 1.7 notes that "[o]rdinarily a lawyer may take inconsistent legal positions in different tribunals at different times on behalf of different clients" but then cautions that a conflict of interest does exist:

[65] Appx570; Appx16
[66] *Upsher-Smith Labs. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005)(citing this "century-old axiom").

> if there is a significant risk that a lawyer's action on behalf of one client will materially limit the lawyer's effectiveness in representing another client in a different case; for example, when a decision favoring one client will create a precedent likely to seriously weaken the position taken on behalf of the other client."[67]

Here, if Cooley was able to convince the USPTO that GW Pharma invented the claims directed to liquid formulations containing at least 95% pure CBD, it would be extremely difficult for United Cannabis to prevail on the validity of claim 10 of the 911 Patent because GW Pharma has an earlier priority date.

The District of Colorado has cited "Conveniently Shifting Positions" as a factor in favor of a fee award.[68] Also, this Court recently affirmed under Rule 36 an exceptional case finding that is analogous here.[69] In *Straight Path*, the patentee argued for a narrow claim construction at the Patent Trial and Appeal Board and Federal Circuit to save the patent from invalidity, but at the same time filed suit in district court relying on a broader claim construction for its infringement theory.[70] The district court found that the patentee's "duplicitous machinations in telling the Federal Circuit one thing and telling [the district court] the opposite on a critical

---

[67] Model Rules of Prof'l Conduct R. 1.7, Comment 24 (2021)
[68] *Andersen Mfg. v. Wyers Prods. Grp.*, Civil Action No. 18-cv-0235-WJM-STV, 2019 U.S. Dist. LEXIS 143730, at *27 (D. Colo. Aug. 23, 2019).
[69] *Straight Path IP Grp., Inc. v. Cisco Sys.*, No. C 16-03463 WHA, 2020 U.S. Dist. LEXIS 87986, at *3 (N.D. Cal. May 19, 2020), *aff'd sub nom. SPIP Litig. Grp., LLC v. Apple, Inc.*, 2021 U.S. App. LEXIS 13839 (Fed. Cir. May 11, 2021)(nonprecedential).
[70] *Straight Path IP Grp. v. Cisco Sys.*, 411 F. Supp. 3d 1026, 1031 (N.D. Cal. 2019)

point make this an 'exceptional case.'"[71] Here, it is undisputed that Cooley attorneys were taking different positions in different forums on a critical issue: who invented a liquid cannabinoid formulation wherein at least 95% of the total cannabinoids is CBD. Liability under Section 285 is, therefore, entirely appropriate here.

The district court's finding in *Straight Path* that the patentee's actions did not give rise to Section 1927 liability[72] is distinguishable. Here, it was not the patentee who was taking two different positions. Here, Cooley took a position before the USPTO on behalf of GW Pharma that, if correct, would be detrimental to United Cannabis in its district court litigation. Earnie Blackmon, United Cannabis's CEO, was asked in his deposition why Cooley was telling the patent office that GW Pharma invented 95% pure CBD in a liquid. His response: "I think you'd have to ask them."[73]

In this case, not only should fees be awarded under Section 285, Cooley should be sanctioned under Section 1927 and the Court's inherent power for taking two different positions in two different tribunals for two different clients over the exact same invention based on which client was paying the bill.

[71] *Id*.
[72] *Id*. at 1035.
[73] Appx713 at p. 86, ll. 7-11.

V. CONCLUSION AND STATEMENT OF RELIEF SOUGHT

1. Pure Hemp was the prevailing party at the district court by virtue of United Cannabis dismissing all of its patent infringement claims with prejudice. At a minimum, Pure Hemp requests that the district court's order denying fees to be overturned as to that finding and remanded for further proceedings.
2. The district court did not conduct an adequate inquiry into the facts and circumstances Pure Hemp identified in its fee motion. Pure Hemp further requests that the Court remand and instruct the district court to conduct a reasonable inquiry into whether the evidence shows that inequitable conduct occurred, as it did in this Court's opinion in *Am. Calcar*, and whether Cooley's inconsistent positions at different tribunals for different clients make this case exceptional.
3. Pure Hemp also requests that this Court consider the facts and circumstances described above and overturn the district court entirely, as it did in *AdjustaCam*[74] and *Rothschild Connected Devices*,[75] because the district court abused its discretion in failing to consider the totality of the circumstances and because its findings were clearly erroneous. This Court

[74] *AdjustaCam*, 861 F.3d at 1362.
[75] *Rothschild Connected Devices*, 858 F.3d at 1390.

should affirmatively hold that Pure Hemp is the prevailing party, that this case is exceptional, that an award of fees and sanctions is appropriate, and remand for a calculation of the amount of reasonable fees that should be awarded.

Dated: March 14, 2022

Respectfully submitted,

/s/ James R. Gourley
James R. Gourley
Carstens & Cahoon, LLP
13760 Noel Road, Suite 900
Dallas, Texas 75240
Tel: (972) 367-2001
Email: gourley@cclaw.com

Attorney for Appellant

ADDENDUM

a. Order Denying Fees (Appx1-3)

b. U.S. Patent No. 9,730,911

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge William J. Martínez

Civil Action No. 18-cv-1922-WJM-NYW

UNITED CANNABIS CORPORATION, a Colorado Corporation,

Plaintiff,

v.

PURE HEMP COLLECTIVE INC., a Colorado Corporation,

Defendant.

ORDER DENYING DEFENDANT PURE HEMP COLLECTIVE INC.'S MOTION FOR ATTORNEY'S FEES

Before the Court is Defendant Pure Hemp Collective Inc.'s Motion for Attorney's Fees ("Motion"), in which Defendant asks the Court to award its attorney's fees of $298,567.60 against Plaintiff United Cannabis Corporation and Plaintiff's counsel, Cooley LLP, jointly and severally. (ECF No. 91 at 1, 3.)

Defendant argues that the Court should award attorney's fees and costs pursuant to 35 U.S.C. § 285. (*Id.* at 8.) Section 285 provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 545 (2014) (defining an "exceptional" case as one "that stands out from others with respect to the substantive strength of a party's litigating position . . . or the unreasonable manner in which the case was litigated"). District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances. *Id.*

Defendant also invokes 28 U.S.C. § 1927 and this Court's inherent authority in support of its request for attorney's fees and costs. (ECF No. 91 at 1, 9.) Section 1927 provides that "[a]ny attorney . . . who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct." Given this statutory language, "[a] court may assess attorney[s'] fees against an attorney under § 1927 if (a) the actions of the attorney multiply the proceedings, and (b) the attorney's actions are vexatious and unreasonable." *Shackelford v. Courtesy Ford, Inc.*, 96 F. Supp. 2d 1140, 1144 (D. Colo. 2000). Ultimately, whether to award § 1927 sanctions is a matter committed to this Court's discretion. *Dominion Video Satellite, Inc. v. Echostar Satellite L.L.C.*, 430 F.3d 1269, 1278–79 (10th Cir. 2005). Likewise, a court has the inherent power to assess such fees as a sanction when a party has acted in bad faith, vexatiously, wantonly, or for oppressive reasons. *See Chambers v. NASCO, Inc.*, 501 U.S. 32, 33 (1991).

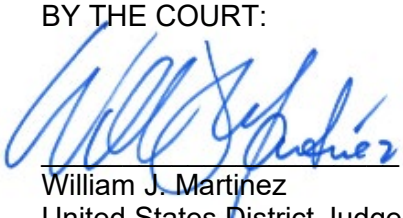
The Court has fully considered all of the parties' arguments regarding Defendant's request for attorney's fees and costs. (ECF Nos. 91, 93, 94, 95.) Ultimately, the Court finds that Defendant has failed to establish that it is the prevailing party under section 285, that this is an "exceptional" case warranting an attorney's fee award, or that Plaintiff's counsel has acted in a vexatious or otherwise unreasonable manner. In making this determination, the Court notes that the parties stipulated to dismissal of this case *before* many of the factual disputes Defendant cites were adjudicated on the merits. (ECF No. 91.) The record on the substantive merits and the materiality of Plaintiff's purportedly inequitable conduct is woefully undeveloped, and as

such, does not paint a persuasive picture for awarding fees.[1] Accordingly, the Court denies Defendant's request for attorney's fees pursuant to section 285, section 1927, or the Court's inherent authority.

For the reasons set forth above, the Court ORDERS that Defendant Pure Hemp Collective Inc.'s Motion for Attorney's Fees (ECF No. 91) is DENIED.

Dated this 22nd day of December, 2021.

BY THE COURT:



William J. Martínez
United States District Judge

[1] Moreover, Defendant's arguments regarding the strength of its litigating position are belied by the fact that the Court denied Defendant's Early Motion for Partial Summary Judgment. (ECF No. 56.)

US009730911B2

(12) **United States Patent**
Verzura et al.

(10) **Patent No.: US 9,730,911 B2**
(45) **Date of Patent: Aug. 15, 2017**

(54) ***CANNABIS* EXTRACTS AND METHODS OF PREPARING AND USING SAME**

(71) Applicant: **United Cannabis Corp.**, Denver, CO (US)

(72) Inventors: **Tony Verzura**, Denver, CO (US); **Earnie Blackmon**, Denver, CO (US)

(73) Assignee: **United Cannabis Corp.**, Denver, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/919,245**

(22) Filed: **Oct. 21, 2015**

(65) **Prior Publication Data**

US 2016/0106705 A1 Apr. 21, 2016

Related U.S. Application Data

(60) Provisional application No. 62/066,795, filed on Oct. 21, 2014, provisional application No. 62/068,278, filed on Oct. 24, 2014.

(51) **Int. Cl.**

A61K 31/35	(2006.01)
A61K 31/353	(2006.01)
A61K 31/192	(2006.01)
A61K 31/352	(2006.01)
A61K 31/05	(2006.01)
A61K 36/185	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 31/353*** (2013.01); ***A61K 31/05*** (2013.01); ***A61K 31/192*** (2013.01); ***A61K 31/352*** (2013.01); ***A61K 36/185*** (2013.01)

(58) **Field of Classification Search**

USPC 514/454, 729, 568

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,949,582	B1	9/2005	Wallace	
2003/0050334	A1	3/2003	Murty et al.	
2011/0092583	A1	4/2011	Murty et al.	
2012/0264818	A1	10/2012	Newland	
2013/0059018	A1*	3/2013	Parolaro	A61K 31/05 424/725
2014/0271940	A1*	9/2014	Wurzer	A61K 36/185 424/725

FOREIGN PATENT DOCUMENTS

CA	2503310	10/2006
DE	10051427	6/2002
EP	2182940	3/2014
GB	2434312	7/2007

OTHER PUBLICATIONS

Calixto et al., "Naturally occurring antinociceptive Substances from Plants" Phytotherapy Research, vol. 14, No. 6, Jan. 1, 2000, pp. 401-418.

Database WPI, Week 201215, Thomson Scientific, CN 102246992A, Nov. 23, 2011.

* cited by examiner

Primary Examiner — Rei-Tsang Shiao

(74) *Attorney, Agent, or Firm* — Cooley LLP; Ivor Elrifi; Cynthia Kozakiewicz

(57) **ABSTRACT**

The invention relates to the extraction of pharmaceutically active components from plant materials, and more particularly to the preparation of a botanical drug substance (BDS) for incorporation in to a medicament. It also relates to a BDS, for use in pharmaceutical formulations. In particular it relates to BDS comprising cannabinoids obtained by extraction from *cannabis*.

36 Claims, No Drawings

CANNABIS EXTRACTS AND METHODS OF PREPARING AND USING SAME

RELATED APPLICATIONS

This application claims priority to, and the benefit of U.S. Provisional Application No. 62/066,795 filed on Oct. 21, 2014 and U.S. Provisional Application No. 62/068,278 filed on Oct. 24, 2014, the contents of which are incorporated by reference in their entireties.

FIELD OF THE INVENTION

This invention relates to the extraction of pharmaceutically active components from plant materials, and more particularly to botanical drug substance (BDS) comprising cannabinoids obtained by extraction from *cannabis*. Methods of using the extracts to treat chronic pain, paralysis, neuropathy, Crohn's Disease, IBS, glaucoma, PTSD, anxiety, seizures, epilepsy, autoimmune disorders autism, tumors, and cancer are also included.

BACKGROUND OF THE INVENTION

Cannabis products have been consumed in various forms for thousands of years. The first descriptions of the medical uses date from Chinese herbal texts in the first century A.D. *Cannabis* products were taken orally in an herbal tea concoction and were used for their pain-relieving and sleep-inducing properties.

There presently exists the need to provide more effective and safer *cannabis* extracts for various medical uses, extraction methods that provide unique active compounds that are useful to treat pain and various medical conditions. Additionally, presently known extraction procedures do not provide the desired active ingredient(s) for the particular medical purpose. The present invention overcomes these limitations and provides other related advantages.

SUMMARY OF THE INVENTION

The invention provides an extract comprising a mixture of at least 95% total cannabinoids, and at least one terpene/flavonoid. The extract contains at least 4, 5, 6, 7 or more cannabinoids. The cannabinoids are selected from tetrahydrocannabinolic acid (THCa), cannabidiolic acid (CBDa), cannabinolic acid (CBNa) cannabichromenic acid (CBCa), tetrahydrocannabinol (THC), cannabinol (CBN), cannabidiol (CBD) or cannabichromene (CBC). In some aspect the cannabinoids are THCa and CBDa and at least two cannabinoids selected from CBNa, CBCa, THC, CBN and CBC. In a preferred embodiment the cannabinoids are THC, CBN, CBC and CBD. In another preferred embodiment the cannabinoids are THCa, CBDa, CBNa and CBCa. In yet another preferred embodiment the cannabinoids are THCa, CBDa, THC, CBN, and CBC.

The terpene/flavonoid is for example, d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, or β-caryophyllene.cannflavin A, apigenin, quercetin or pulegone.

Also provided by the invention are formulations containing the extracts according to the invention. For example the formulation contains any of the extracts according to the invention infused with a medium chain triglyceride (MCT). The MCT is for example, NEOBEE 895.

Preferably, the pH of the formulation is at least pH 8.0.

In some formulations the concentration of THCa is greater than or equal to 95%; CBDa is less than 1%; CBNa is less than 3%; and CBCa is less than 1%. Optionally the formulation further contains d-limonene, linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, cannflavin A, apigenin, quercetin

In other formulations the concentration of THCa is less than or equal to 35%; CBDa is greater than or equal to 60%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%. Optionally, the formulation further contains d-limonene, linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, cannflavin A, apigenin, quercetin

In another formulation the concentration of THCa is greater than or equal to 40%; CBDa is greater than or equal to 40%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%. Optionally, the formulation further contains β-myrcene, ρ-caryophyllene, pulegone, α-terpineol, β-sitosterol, cannflavin A, apigenin, quercetin

In yet another formulation the concentration of THC is less than or equal to 9%; CBD is greater than or equal to 40%; CBN is greater than or equal to 40%; and CBS is less than 1%. Optionally, the formulation further contains 3-myrcene, β-caryophyllene, pulegone, α-terpineol, β-sitosterol, cannflavin A, apigenin, quercetin.

In various aspects the formulation of the invention are formulated for r oral, sublingual, buccal, or topical administration. The sublingual formulation further contains a sweetener such as a *stevia* extract. Optionally, the sublingual formulation further contains lemon oil, orange oil or both.

In other aspects the invention provides a method of preparing a *cannabis* extract providing fresh or live *cannabis* plant material; extracting the cannabinoids from the plant material to produce a first extract; winterizing and purging the winterized extract. Optionally, the method further includes decarboxylating the phytocannabinoids prior to extraction. The decarboxylation is accomplished for example, by heating the dried plant material at a temperature of about 221° F. for at least 15 minutes followed by heating at about 284° F. for at least 45 minutes. In some aspects the winterized extract is heated at 284° F. for at about 45-74 minutes followed by heating at about 293° F. for at least about 55-90 minutes.

Extraction is for example by hydrocarbon extraction. Winterizing includes adding cold ethanol to the first extract or storing the first extract at a temperature of about −20° to about −75° F. for about 48 hours to produce a waxy precipitate and removing the waxy precipitate by filtration. Optionally, the winterized extract is filtered through activated charcoal.

The *cannabis* plant material consists of flowers or flowers and leaves. In some aspects the *cannabis* plant material is frozen at a temperature between at least −10° F. to −50° F. for at least 36 hours prior to being extracted. Preferably, the *cannabis* plant material has been propagated from a single seed source or a tissue culture with specific ratios of cannabinoids. In some aspects the *cannabis* plant material is derived from a *cannabis* strain having a minimum of 15% THC and less that 1% CBD. In others aspect the *cannabis* plant material is derived from Sour Tsunami×Catatonic Sour Tsunami×Sour Tsunami, Sour Tsunami, Harlequin, R4 ACDC strains. In yet other as aspects the *cannabis* plant material is derived from CBD1, Sour Pineapple, CBD Diesel, Harlequin, ACDC or R4. In yet a further aspect the *cannabis* plant material is derived from Sour Tsunami×

Catatonic, Sour Tsunami×Sour Tsunami, Sour Tsunami, Harlequin, R4, Swiss Gold, ACDC, CBD1, Sour Pineapple, or CBD Diesel.

The invention further provides a method for preparing *cannabis* juice by blanching fresh *cannabis* leaves obtained from a *cannabis* plant in the vegetative stage in cold water; juicing the leaves in a cold press juicer or masticating juicer; and filtering the juice through a filter to remove particulates. Optionally, filter juice is freeze dried.

The juicer is for example, a cold press juicer or a masticating juicer. Also included in the invention is juice produced according to the method of the invention. In some embodiments the *cannabis* juice is obtained from *cannabis* flowers, *cannabis* roots or both.

The invention also provides method of relieving symptoms associated with anxiety, post traumatic stress disorder, chronic pain, or opiate dependency, paralysis, neuropathy, Crohns disease, inflammatory bowel disorders, glaucoma, seizures, epilepsy, autism, or cancer comprising administering to a subject in need thereof one or more of the formulations or juice according to the invention. The formulations are administered four times daily. For example the formulation is administered in the morning; afternoon, evening and at bedtime.

In specific embodiments the invention provides a method of treating cancer by administering to a subject a total daily doses of: 20 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days; 40 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days; 80 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days; 120 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days; and 160 mg of cannabinoid extract and 100 mg of raw *cannabis* juice for seven days. In some aspects the method further includes administering a total daily dose of 200 mg cannabinoid extract and 100 mg of raw *cannabis* juice every day thereafter or administering 200 mg of cannabinoid extract and 100 mg of raw *cannabis* juice for seven days; and 400 mg of cannabinoid extract and 100 mg of raw *cannabis* juice every day thereafter.

In another embodiment the invention provides method of treating opioid dependency by reducing the amount of opiates used per day by at least 10% and administering to a subject a total daily doses of: 31 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; 56 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; 84 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for fourteen days; 104 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; 89 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; 69 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; 49 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days; and 41 mg of cannabinoid extract and 50 mg of raw *cannabis* for fourteen days.

Optionally, the method further includes administering a total daily dose of 36 mg cannabinoid extract and 25 mg of raw *cannabis* every day thereafter and a single dose of 50 mg raw *cannabis* every three days.

In another embodiment, the invention provides a method of treating anxiety/PTSD by administering to a subject a total daily doses of about 28 mg to 42 mg of cannabinoid extract.

In a further embodiment, the invention includes a method of treating chronic pain by administering to a subject a total daily doses of about 36 mg to 48 mg of cannabinoid extract.

The formulations are administered four times daily. For example, the formulation is administered in the morning; afternoon, evening and at bedtime.

Other features and advantages of the invention will be apparent from and are encompassed by the following detailed description and claims.

DETAILED DESCRIPTION

The present invention is based in part upon extraction procedures and delivery approaches that allow selective utilization of various cannabinoid molecules and terpenes from the whole *cannabis sativa* plant. These various cannabinoid compounds are designed to selectively affect various cannabinoid receptors in the nervous system, immune system and other tissues. The extract is an oil-based whole plant product that contains inactive and active compounds contained in the *cannabis* plant such as cannabinoids, terpenes and/or flavonoids. Compositions of the invention and methods of extraction disclosed herein provide an extract with specific physiological properties that are mediated through separate pathways and receptors, which provide numerous benefits and advantages.

The extracts and/or delivery methods of the invention allows a wide range of prevention, treatment and management options for patients. In some aspects the delivery methods of the invention employs micro-dosing with a stacking method of cannabinoid administration week by week until a certain saturation point that is based on response, weight, and monthly-quarterly test results.

Surprisingly, it was discovered that the age or the *cannabis* plant material, the temperature in which it is stored and processed is critical and the ratio of the specific cannabinoids extract is critical to effectiveness of the final formulation. Importantly, for an extract to maintain non-psychoactive properties the *cannabis* plant material is never heated above 160° F. Preferably, the non-psychoactive extracts according to the invention are formulated at 110° F. or below.

Cannabis is a genus of flowering plants that includes three different species, *Cannabis sativa, Cannabis indica* and *Cannabis ruderalis*. The term "*Cannabis* plant(s)" encompasses wild type *Cannabis* and also variants thereof, including *cannabis* chemovars which naturally contain different amounts of the individual cannabinoids. For example, some *Cannabis* strains have been bred to produce minimal levels of THC, the principal psychoactive constituent responsible for the high associated with it and other strains have been selectively bred to produce high levels of THC and other psychoactive cannabinoids.

Cannabis plants produce a unique family of terpenophenolic compounds called cannabinoids, which produce the "high" one experiences from consuming marijuana. There are 483 identifiable chemical constituents known to exist in the *cannabis* plant, and at least 85 different cannabinoids have been isolated from the plant. The two cannabinoids usually produced in greatest abundance are cannabidiol (CBD) and/or Δ9-tetrahydrocannabinol (THC), but only THC is psychoactive. *Cannabis* plants are categorized by their chemical phenotype or "chemotype," based on the overall amount of THC produced, and on the ratio of THC to CBD. Although overall cannabinoid production is influenced by environmental factors, the THC/CBD ratio is genetically determined and remains fixed throughout the life of a plant. Non-drug plants produce relatively low levels of THC and high levels of CBD, while drug plants produce high levels of THC and low levels of CBD.

The best studied cannabinoids include tetrahydrocannabinol (THC), cannabidiol (CBD) and cannabinol (CBN). Other cannabinoids include for example, cannabichromene (CBC), cannabigerol (CBG) cannabinidiol (CBND), Cannabicyclol (CBL), Cannabivarin (CBV), Tetrahydrocannabivarin (THCV), Cannabidivarin (CBDV), Cannabichromevarin (CBCV) Cannabigerovarin (CBGV), Cannabigerol Monomethyl Ether (CBGM).

Cannabinoids are derived from their respective 2-carboxylic acids (2-COOH) by decarboxylation (catalyzed by heat, light, or alkaline conditions). As a general rule, the carboxylic acids form of the cannabinoid have the function of a biosynthetic precursor.

As used herein THC, CBD, CBN, CBC, CBG, CBND, CBL, CBV, THCV, CBDV, CBCV, CBGV and CBGM refer to the decarboxylated form of the cannabinoid. Whereas, THCa, CBDa, CBNa, CBCa, CBGa, CBNDa, CBLa, CBVa, THCVa, CBDVa, CBCVa, CBGVa and CBGM refer to the acid form of the cannabinoid.

Tetrahydrocannabinol (THC) is the primary psychoactive component of the *Cannabis* plant. THC is only psychoactive in is decarboxylated state. The carboxylic acid form (THCa) is non-psychoactive.

Delta-9-tetrahydrocannabinol (Δ9-THC, THC) and delta-8-tetrahydrocannabinol (Δ8-THC), mimic the action of anandamide, a neurotransmitter produced naturally in the body. These two THCs produce the effects associated with *cannabis* by binding to the CB1 cannabinoid receptors in the brain. THC appears to ease moderate pain (analgesic) and to be neuroprotective, while also offering the potential to reduce neuroinflammation and to stimulate neurogenesis. THC has approximately equal affinity for the CB1 and CB2 receptors.

Cannabidiol (CBD) is not psychoactive, and was thought not to affect the psychoactivity of THC. However, recent evidence shows that smokers of *cannabis* with a higher CBD/THC ratio were less likely to experience schizophrenia-like symptoms.[15] This is supported by psychological tests, in which participants experience less intense psychotic-like effects when intravenous THC was co-administered with CBD (as measured with a PANSS test). Cannabidiol has little affinity for CB1 and CB2 receptors but acts as an indirect antagonist of cannabinoid agonists. Recently it was found to be an antagonist at the putative new cannabinoid receptor, GPR55, a GPCR expressed in the caudate nucleus and putamen. Cannabidiol has also been shown to act as a 5-HT1A receptor agonist, an action that is involved in its antidepressant, anxiolytic, and neuroprotective effects.

It appears to relieve convulsion, inflammation, anxiety, and nausea. CBD has a greater affinity for the CB2 receptor than for the CB1 receptor. CBD shares a precursor with THC and is the main cannabinoid in low-THC *Cannabis* strains. CBD apparently plays a role in preventing the short-term memory loss associated with THC in mammals.

Cannabinol (CBN) is the primary product of THC degradation, and there is usually little of it in a fresh plant. CBN content increases as THC degrades in storage, and with exposure to light and air. It is only mildly psychoactive. Its affinity to the CB2 receptor is higher than for the CB1 receptor

Cannabigerol (CBG) is non-psychotomimetic but still affects the overall effects of *Cannabis*. It acts as an α2-adrenergic receptor agonist, 5-HT1A receptor antagonist, and CB1 receptor antagonist.[31] It also binds to the CB2 receptor.[31]

Tetrahydrocannabivarin (THCV) is prevalent in certain central Asian and southern African strains of *Cannabis*. It is an antagonist of THC at CB1 receptors and attenuates the psychoactive effects of THC.

Cannabidivarin (CBDV) is usually a minor constituent of the cannabinoid profile.

Cannabichromene (CBC) is non-psychoactive and does not affect the psychoactivity of THC. More common in tropical *cannabis* varieties. Effects include anti-inflammatory and analgesic.

In addition to cannabinoids, *cannabis* plants produce terpenes, a diverse group of organic hydrocarbons that are the building blocks of the cannabinoids.

Over 100 different terpenes have been identified in the *cannabis* plant, and every strain tends toward a unique terpene type and composition. The terpenes act synergistically with the cannabinoids to provide a therapeutic effect. Examples of some common terpenes found in *Cannabis* include:

Borneol—menthol, camphor, pine, woody. Can be easily converted into menthol. It is considered a "calming sedative" in Chinese medicine. It is directed for fatigue, recovery from illness and stress.

Caryophyllene—spicy, sweet, woody, clove, camphor, peppery. It binds weakly to CB2 receptor. As a topical it is one of the constituents of an anti-inflammatory and analgesic treatment for toothache. In high amounts, it's a calcium and potassium ion channel blocker. As a result, it impedes the pressure exerted by heart muscles.

Cineole/Eucalyptol—spicy, camphor, refreshing, minty. It is used to increase circulation, pain relief and easily crosses the blood-brain-barrier to trigger fast olfactory reaction.

Delta3Carene—sweet, pine, cedar, woodsy, pungent. In aroma therapy, cypress oil, high in D-3-carene, is used to dry excess fluids, tears, running noses, excess menstrual flow and perspiration.

Limonene—citrus (orange, tangerine, lemon, and grapefruit), rosemary, juniper, peppermint Repulsive to predators. Found in the rinds of many fruits and flowers. With the presence of other certain terpenes, Limonene can be an anti-bacterial, anti-fungal, anti-depressant and anti-carcinogen. It can synergistically promote the absorption of other terpenes by quickly penetrating cell membranes. The result can be increased systolic blood pressure.

Linolool—floral (spring flowers), lily, citrus and candied spice. Possesses anti-anxiety and sedative properties.

Myrcene—clove like, earthy, green-vegetative, citrus, fruity with tropical mango and minty nuances. The most prevalent terpene found in most varieties of marijuana. It's a building block for menthol, citronella, and geraniol. It possesses antimicrobial, antiseptic, analgesic, antioxidant, anti-carcinogen, anti depressant, anti-inflammatory, and muscle relaxing effects. Myrcene affects the permeability of the cell membranes, allowing more THC to reach brain cells.

Pinene—Alpha: pine needles, rosemary Beta: dill, parsley, rosemary, basil, yarrow, rose, hops, the familiar odor associated with pine trees and their resins. Pinene can increase mental focus and energy, as well as act as an expectorant, bronchodilator, and topical antiseptic. It easily crosses the blood-brain barrier where it inhibits activity of acetylcholinesterase, which destroys acetylcholine, an information transfer molecule, resulting in better memory. It may counteract THC's activity, which leads to low acetylcholine levels.

Pulegone—mint, camphor, rosemary, candy. Pulegone is an acetylcholinesterase inhibitor. That is, it stops the action of the protein that destroys acetylcholine, which is used by the brain to store memories.

In various aspects the invention provides *cannabis* extracts with predefined ratios of cannabinoids. Standard conditions for cannabinoid assays, and methods of calculating cannabinoid content (as %) are well known in the art.

The extracts are mixture of at least 95% total cannabinoids and include terpenes and/or flavonoids. Preferably the extracts contains a mixture of at least cannabinoids four cannabinoid such as tetrahydrocannabinolic acid (THCa), cannabidiolic acid (CBDa), cannabinolic acid (CBNa) cannabichromenic acid (CBCa), tetrahydrocannabinol (THC), cannabinol (CBN), cannabidiol (CBD) and cannabichromene (CBC).

In some embodiments the extract contains THCa and CBDa and at least two cannabinoids selected from CBNa, CBCa, THC, CBN and CBC. In other embodiments the extract includes THC, CBN, CBC and CBD. In further embodiments the extract includes THCa, CBDa, CBNa and CBCa. In other embodiments the extract includes THCa, CBDa, THC, CBN, and CBC.

The terpene and/or flavonoids in the extract include for example, terpene is linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene.d-limonene, cannflavin A, apigenin, quercetin or pulegone.

The extracts of the invention may be formulated with one or more pharmaceutically acceptable carriers, diluents or excipients or deposited on a pharmaceutically acceptable surface for vaporisation in order to produce pharmaceutical formulations containing cannabinoids as the pharmaceutically active agents.

Therefore, in a further aspect the invention provides a method of making a pharmaceutical composition comprising, as an active agent, a substance which is an extract from at least one *cannabis* plant variety.

Separate extracts may be prepared from single *cannabis* plant varieties having differing cannabinoid content (e.g. high THC and high CBD plants) and then mixed or blended together prior to formulation to produce the final pharmaceutical composition. This approach is preferred if, for example, it is desired to achieve a defined ratio by weight of individual cannabinoids in the final formulation. Alternatively, plant material from one or more *cannabis* plant varieties of defined cannabinoid content may be mixed together prior to extraction of a single botanical drug substance having the desired cannabinoid content, which may then be formulated into a final pharmaceutical composition.

The extract may be formulated with any convenient pharmaceutically acceptable diluents, carriers or excipients to produce a pharmaceutical composition. The choice of diluents, carriers or excipients will depend on the desired dosage form, which may in turn be dependent on the intended route of administration to a patient. Preferred dosage forms include, liquid dosage forms for administration via pump-action or aerosol sprays, tablets, pastilles, gels, capsules, suppositories, powders, etc. and vaporizers. Such dosage forms may be prepared in accordance with standard principles of pharmaceutical formulation, known to those skilled in the art.

Liquid formulations are particularly preferred. A particularly preferred formulation for administration of cannabinoids, though not intended to be limiting to the invention, is a liquid formulation of the extracts according to the invention infused with a medium chain triglyceride (MCT). The MCT suitable for human consumption. The MCT may be composed of any combinations of C-6; C-8; C-10:C12 fatty acids. For example, the MCT is composed of 97%:3% C-8:C10; C-12 fatty acids (e.g., NEOBEE 895). Preferably the pH of the formulation is at least pH 8.0. The formulations are suitable for oral, sublingual, buccal, or topical administration. When used for sublingual administration the formulation optionally comprises a sweetener such as *stevia* extract and or a flavoring such as for example lemon oil, orange oil or both.

A preferred formulation includes a cannabinoid mixture where THCa is greater than or equal to 95%; a CBDa is less than 1%; CBNa is less than 3%; and CBCa is less than 1%. In some aspects the formulation further includes d-limonene, linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, cannflavin A, apigenin, and quercetin. This preferred formulation is referred to herein as PRANA 1.

Another preferred formulation includes a cannabinoid mixture where the THCa is less than or equal to 35%; CBDa is greater than or equal to 60%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%. In some aspects the formulation further includes d-limonene, linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, cannflavin A, apigenin, and quercetin. This preferred formulation is referred to herein as PRANA 2.

In yet another preferred embodiment the formulation includes a cannabinoid mixture where the THCa is greater than or equal to 40%; CBDa is greater than or equal to 40%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%. In some aspects the formulation further includes β-myrcene, β-caryophyllene, pulegone, α-terpineol, β-sitosterol, cannflavin A, apigenin, and quercetin. This preferred formulation is referred to herein as PRANA 3.

In a further embodiment the formulation includes a cannabinoid mixture THC is less than or equal to 9%; CBD is greater than or equal to 40%; CBN is greater than or equal to 40%; and CBS is less than 1%. In some aspects the formulation further includes β-myrcene, β-caryophyllene, pulegone, α-terpineol, β-sitosterol, cannflavin A, apigenin, and quercetin. This preferred formulation is referred to herein as PRANA 4.

The extract is formulated for oral use (e.g. capsules) in dosage forms that provide 5 mg, 10 mg, 20 mg, or 50 mg of total cannabinoids per dose. For sublingual use, the extract is formulated to provide 0.5, 1 mg, or 2 mg, per drop.

In some applications, the patient may find it advantageous to activate (i.e., decarboxylate) the inactive (i.e. carboxylic acid form) cannabinoids in the extracts and formulations of the invention. The inactive cannabinoids (e.g., THCa and CBDa) of the extracts and formulation of the invention can be converted to active cannabinoids (THC and CBD) by heating the extracts and formulation at a temperature above 160° F. For example, a vessel containing the extracts and formulations of the invention are placed in boiling water (212° F.) for about 30 minutes.

According the invention further contemplates extracts and formulations thereof having the same ratio of cannabinoids as PRANA 1, PRANA 2 and PRANA3 where the THA and the CBD is in its activated decarboxylated form.

The methods of the invention may be used to prepare a cannabinoid-rich extract from *cannabis* plant material. The method includes providing fresh or live *cannabis* plant material; extracting the cannabinoids from the fresh or live plant material to produce a first extract; winterizing the first to produce a winterized extract and purging the winterized

extract to produce a *cannabis* extract. Optionally, the method includes decarboxylating the phytocannabinoids prior the extraction step.

Decarboxylation of cannabinoid acids is a function of time and temperature, thus at higher temperatures a shorter period of time will be taken for complete decarboxylation of a given amount of cannabinoid acid. In selecting appropriate conditions for decarboxylation consideration must, however, be given to minimising thermal degradation of the desirable, pharmacological cannabinoids into undesirable degradation products, particularly thermal degradation of THC to cannabinol (CBN). Preferably, decarboxylation is carried out in a multi-step heating process. For example, Phytocannabinoids are decarboxylated for example by heating the dried plant material at a temperature of about 221° F. for at least 15 minutes followed by heating at about 284° F. for at least 45 minutes. Other suitable methods of decarboxylating phytocannabinoids known in the art may be used.

In some aspects resultant *cannabis* extract is heated at 284° F. for at about 45-74 minutes followed by heating at about 293° F. for at least about 55-90 minutes.

The *cannabis* plant material consists of flowers or flowers and leaves. Preferably, the *cannabis* plant material is frozen at a temperature between at least −10° F. to −50° F. for at least 36 hours prior to being dried.

The *cannabis* plant material has been propagated from a single seed source or a tissue culture or clone with specific ratios of cannabinoids.

Any suitable method for extraction known in the art may be used. For example extraction is hydrocarbon extraction, supercritical C02 or NEOBEE 896 MCT.

The first extract may be winterizing by any method known in the art. For example the first extract is winterized by comprises adding cold ethanol or by storing the first extract at temperature of about −20° F. to about −75° F. for about 48 hours. Winterization produces a waxy precipitate. The waxy precipitate is removed by filtration. Optionally, the winterized extract through activated charcoal.

In some aspects the *cannabis* plant material is derived from a *cannabis* strain having a minimum of 15% THC and less that 1% CBD. In other aspects the *cannabis* plant material is derived from *cannabis* strains having a minimum of 10% CBD and less than 10% THC. For example the *cannabis* plant material is derived from Sour Tsunami× Catatonic Sour Tsunami×Sour Tsunami, Sour Tsunami, Harlequin, R4 or ACDC strains. In other embodiments the *cannabis* plant material is derived from CBD1, Sour Pineapple, CBD Diesel, Harlequin, ACDC or R4. In yet another embodiment the *cannabis* plant material is derived from Sour Tsunami×Catatonic, Sour Tsunami×Sour Tsunami, Sour Tsunami, Harlequin, R4, Swiss Gold, ACDC, CBD1, Sour Pineapple, or CBD Diesel.

The invention also provides a method for preparing *cannabis* juice comprising blanching fresh *cannabis* leaves obtained from a *cannabis* plant in the vegetative stage in cold water; juicing the leaves in a cold press juicer or masticating juicer; filtering the juice through a filter to remove particulates. Optionally, the juice freeze dried. The juicer is a cold press juicer or a masticating juicer. In some aspects the juice further includes *cannabis* juice obtained from *cannabis* flowers, *cannabis* roots or both.

The juice of raw *cannabis* provides unique healing benefits. Plant chemicals known as cannabinoid acids such as CBD-acids, and THC-acids break down quickly after harvest, so these compounds are not available in traditional preparations such as cooked 'medibles', smoking, or vaporizing The healing benefits of cannabinoid-acids are only present for a short period of time before the chemicals break down, so juicing needs to be done quickly after harvest. Fan leaves should make up the majority of the juice, and adding a small amount of *cannabis* flowers can be beneficial.

Cannabis extracts and juice have wide-ranging beneficial effects on a number of medical conditions.

Chronic pain, paralysis, neuropathy, Crohn's Disease, inflammatory bowel disorders (IBS and IBD), glaucoma, PTSD, anxiety, seizures, epilepsy, autoimmune disorders, autism, tumors, and cancer have all been shown by several studies to be controlled by use of *Cannabis*. In addition, nausea and vomiting that are unresponsive to other medications have been shown to be helped through the use of *Cannabis*. Dependency on opiates have also been shown to be controlled by the use of *Cannabis*

Accordingly the invention also includes methods of alleviating a symptom associated with anxiety, post-traumatic stress disorder, chronic pain, or opiate dependency, paralysis, neuropathy, Crohn's disease, inflammatory bowel disorders, glaucoma, seizures, epilepsy, autism, or cancer comprising administering to a subject any one of the formulation according to the invention. In some embodiments the subject receives both a formulation containing a *cannabis* extract and raw *cannabis* in the form of a juice.

In some embodiments the formulation are administered four times daily. For example, the formulations are administered in the morning, afternoon, evening and at bedtime. The formulations are administered such that the ratio of cannabinoids are different depending upon the time of day administered. For example, formulations containing lower amounts of THC (and higher amounts of THCa) are administered during waking hours of the day. Whereas, formulations containing higher amounts of THC (and lower amounts of THCa) are administered prior to bedtime. Exemplary day time formulations include a cannabinoid mixture where THCa is greater than or equal to 95%; a CBDa is less than 1%; CBNa is less than 3%; and CBCa is less than 1%; a cannabinoid mixture where the THCa is less than or equal to 35%; CBDa is greater than or equal to 60%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%; or a cannabinoid mixture where the THCa is greater than or equal to 40%; CBDa is greater than or equal to 40%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1%. An exemplary bedtime formulation includes a cannabinoid mixture THC is less than or equal to 9%; CBD is greater than or equal to 40%; CBN is greater than or equal to 40%; and CBS is less than 1%.

Preferably a formulation including a cannabinoid mixture where THCa is greater than or equal to 95%; a CBDa is less than 1%; CBNa is less than 3%; and CBCa is less than 1% is administered in the morning. Preferably a cannabinoid mixture where the THCa is less than or equal to 35%; CBDa is greater than or equal to 60%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1% is administered in the afternoon. Preferably, a cannabinoid mixture where the THCa is greater than or equal to 40%; CBDa is greater than or equal to 40%; THC is less than 1%; CBN is less than 1%; and CBC is less than 1% is administered in the evening.

In various aspects the method of the invention include administering the cannabinoids containing compounds by employing an escalating dosing regimen where the total amount of cannabinoids are increased over time. For example, the amount of cannabinoids administered is increased week by week until a certain saturation point that is based on response, weight, and monthly-quarterly test results. To treat opioid dependency, opiates are gradually replaced cannabinoids.

In a preferred method cancer is treated by administering to a subject a total daily doses of:

a. 20 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days;
b. 40 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days;
c. 80 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days;
d. 120 mg of cannabinoid extract and 50 mg of raw *cannabis* juice for seven days; and
e. 160 mg of cannabinoid extract and 100 mg of raw *cannabis* juice for seven days.

In some embodiments, this dosing regimen is followed by administering the subject a total daily dose of 200 mg cannabinoid extract and 100 mg of raw *cannabis* juice every day thereafter. In another embodiment this dosing regimen is followed by administering the subject 200 mg of cannabinoid extract and 100 mg of raw *cannabis* juice for seven days; and 400 mg of cannabinoid extract and 100 mg of raw *cannabis* juice every day thereafter.

EXAMPLES

Example 1: Preparation & Storage of *Cannabis*

Fresh *cannabis* plant material (flowers/flower leaves) is harvested from plants propagated from cuttings taken from the mother plants, originating from a single seed source or tissue culture with specific starting ratio's of cannabinoids

Cannabis Plant material (flowers/flower leaves) is stored in a fresh frozen state immediately after harvesting.

Preferably the plant material is flash frozen for 10 minutes at a temperature between 10° F. and −50° F. The plant material is stored in vacuum seal bags for a minimum of 36 hrs prior to extraction. The starting *cannabis* plant material is extracted at a 90% cannabinoid and/or phytocannabinoid concentrated form.

Example 2: Extraction of Inactive Cannabinoids

Cannabis flowers stored in a flash frozen state (see Example 1), and gently spread apart on curing screens while still in a frozen state. Gently break apart and spread the fresh frozen plant material into small sized pieces less than 0.7 inches on a 160 u-220 u screen to be air dried out.

The plant material (inactive plant matter) is placed in a stainless steel cylinder inside a closed loop hydrocarbon extraction machine such as the Emotek Obe Dos, or equal supercritical CO_2 extraction equipment/methods that meet these specific requirements.

Liquid hydrocarbon (99%) is run thru the product and held under pressure of (45 pounds of pressure) for approximately 45 min at a temperature −20° F. fahrenheit to −75° F.

The result material is winterized to remove inert waxy material. Winterization is accomplished by applying a secondary gas to the liquid hydrocarbon; a cold ethanol wash that is filtered out, or by storing the extract solution at −20° F. to −75° F. for approximately 48 hrs. The resultant waxy precipitate is removed by filtration through a twenty μm membrane and passed through activated charcoal.

Finally, the extract is purged under a vacuum pressurized unit Across International Digital Vacuum Drying Oven with a solvent rated recovery pump with a min ½ hp 3425 rip oil-less compressor for approximately 48 hrs.

The final product is removed and stored in amber glass storage containers without light exposure and stored at temps below 40° F. until needed for formulation of products.

Example 3: Extraction of Active Cannabinoids

Cannabis flowers are air dried as in Example 2. Once the *cannabis* flowers are air dried the *cannabis* plant material is placed in a scientific sterile containment oven for 15 min @ 221° F. degrees, and again at 284° F. degrees for 45 min. The process in order decarboxylates the phytocannabinoids. Once the *cannabis* plant material has been decarboxylated it is extracted in an ACTIVE

The fresh *cannabis* plant material (ACTIVE plant material) is placed in a stainless steel cylinder inside a closed loop hydrocarbon extraction Liquid hydrocarbon (99%) is run thru the product and held under pressure of (45 pounds of pressure) for approximately 45 min at a temperature −20° F. fahrenheit to −75° F.

The result material is winterized to remove inert waxy material. Winterization is accomplished by applying a secondary gas to the liquid hydrocarbon; a cold ethanol wash that is filtered out, or by storing the extract solution at −20° F. to −75° F. for approximately 48 hrs. The resultant waxy precipitate is removed by filtration through a twenty μm membrane and passed through activated charcoal.

Finally, the extract is purged under a vacuum pressurized unit Across International Digital Vacuum Drying Oven with a solvent rated recovery pump with a min ½ hp 3425 rip oil-less compressor for approximately 48 hrs.

The resultant decarboxylated CBD:THC oil is converted to CBD:CBN (defined as >90% CBD:THC) oil by heating the oil at 284° F. for 45-75 minutes, and a second temperature at 293° F. for 55 min-90 min.

The final product is removed and stored in amber glass storage containers without light exposure and stored at temps below 40° F. until needed for formulation of products.

Example 3: Extraction Using NEOBEE 895 MCT

Start with cured and dried *cannabis* flowers, flower rosin, hash rosin, hashish, or kif with specific starting ratio's of cannabinoids 1:1, 2:1, 3:1, 4:1, 8:1, 18:1, 20:1, 30:1, 50:1, 70:1. *Cannabis* flowers should be dried out with a moisture content of below 3% and gently broken apart into small sized pieces less then 0.7 inches, or finely milled into 2 mm to 3 mm sized pieces. *Cannabis* flowers, flower rosin, hash rosin, hashish, or kif are combined with NEOBEE 895 MCT. The ratio of *cannabis* to MCT is determined based on the starting material, test results, ratio's, and desired mg per ml outcome. Example 50 g of 20% *Cannabis* flowers combined with 100 ml of MCT oil. The MCT Oil and starting *cannabis* material is heated together in a brewer, double boiler, or on a heat plate at 41 celsius/106 fahrenheit for a minimum of 3 hrs in order to extract and infuse the desired cannabinoids into the MCT oil. The oil is strained thru a 15 micron stainless steel filter, or silk screen to separate the *cannabis* content from the oil. Utilizing a Buchner funnel and 5 micron filtration system under vacuum will provide the best results for flirtation. The soaked *cannabis* content is pressed to remove all remaining oil, filtered, and added back to the concentrated infused THCa and/or CBDa NEOBEE 895 MCT mixture. This initial mixture is considered a INACTIVE state since the cannabinoids are still in the acid forms of THCa and/or CBDa. The infused *cannabis* and NEOBEE 895 MCT oil can be heated at 105 celsius/221 fahrenheit for 15 min, and repeated at 140 celsius/284 fahrenheit 45 min-120 min to ACTIVATE the phytocannabinoids into

THC and/or CBD. Decarboxylate *cannabis* flowers, flower rosin, hash rosin, hasish, or kif THC, or CBN, can also be combined to the NEOBEE 895 MCT and heated together at 41 celsius/106 fahrenheit for a minimum of 3 hrs in order to infuse the ACTIVE content into the MCT oil. This process is used to create all products with specific ratio's and milligram to milliliter dosages for capsules, sublingual's, topical, transdermal, etc.

Example 4: Flower & Hash Rosin Extraction

Cannabis flowers are cured until moisture is below 10%. Once the *cannabis* flowers are air dried the *cannabis* plant material is placed in a stainless steel, or nylon silk screen sleeves with a micron ratings ranging including 15 u, 25 u, 90 u, and 120 u. Desired micron rating is used based on the starting material flower vs separated trichome heads only known as bubble hash or kif. The flowers, hash, or kif in these sleeves are placed between PTFE 3× flourmer coated sheets, or non-stick parchment paper. The sheets are a min of 2× wider then the nylon or stainless steel screens to collect the extracted cannabinoid oils and resin. A mechanical heat platen press is used with min pressure of 2500 psi with heat applied at ranges between 100-300 degree's for a range of 4 seconds to 3 min depending on the desired out come. This process mechanically separates the cannabinoids and terpenes present in the raw *cannabis* flowers with concentrations of THCa, THC, CBDa, CBD, CBGa, CBG, CBN, CBL. The resin is collected from the PTFE or non stick parchment paper, weighed, and stored in a plastic seal bag or glass pyrex at temperatures of 32 degrees fahrenheit or below. This type of mechanically separated *cannabis* resin and extract is later combined with NEOBEE 895 MCT to make desired formulations, ratio's, and concentrations for the various delivery methods described in this document i.e. capsule, topical, transdermal, sublingual.

Example 5: Preparation of Raw Cannabinoids

Plants with high CBD content are best for juicing as they contain more CBD-acids than non-CBD producing strains.

Process:

1. We remove ONLY fresh *cannabis* leaves during vegetation NOT during the flowering cycle.
2. Leaves are blanched in cold water for cleaning
3. Leaves are then juiced using a cold press juicer or commercial masticating juice
4. The juice is filtered thru a stainless steel filter to remove any particulates.
5. Juice is immediately poured into 1 oz containers or 10 oz containers and freeze-dried at −50° F. degrees.
6. Freeze-dried *cannabis* juice can be used in capsule form, packets, or infused with a medical food.

Example 6: Formulation of *Cannabis* Extracts

Mix 1 gram of *cannabis* oil produced by the above methods with a min of 95% total cannabinoid concentration per 40 ml of NEOBEE 895 for approximately 24 hrs at a temperature under 90° F. but not lower than 70° F. without exposure to light. The resultant infusion is mixed with NEOBEE 895 to produce capsules at 5 mg, 10 mg, 20 mg, and 50 mg total cannabinoids. For subligual formulations 0.5 g or 350 mg of the resultant infusion is combined with 9 ml of NEOBEE 895 and 1 ml of natural sweeteners and flavor additives. (*stevia*, truvia, xyotol, lemon, orange)

Example 7: Exemplary Stacking Protocol for Cancer/Tumor Treatment and Management

Week #1
Morning:
Frozen ¼ ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (50 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
5 mg Prana P1 Capsules
Afternoon:
5 mg Prana P2 Capsules
Dinner:
5 mg Prana P3 Capsules
Bedtime: (30 min Prior)
5 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 20 mg+50 mg Raw
Week #2
Morning:
Frozen ¼ ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (50 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
10 mg Prana P1 Capsules
Afternoon:
10 mg Prana P2 Capsules
Dinner:
10 mg Prana P3 Capsules
Bedtime: (30 min Prior)
10 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 40 mg+50 mg Raw
Week #3 (Min Holding Dose)
Morning:
Frozen ¼ ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (50 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
20 mg Prana P1 Capsules
Afternoon:
20 mg Prana P2 Capsules
Dinner:
20 mg Prana P3 Capsules
Bedtime: (30 min Prior)
20 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 80 mg+50 mg Raw
Week #4
Morning:
Frozen ¼ ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (50 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
30 mg Prana P1 Capsules
Afternoon:
30 mg Prana P2 Capsules
Dinner:
30 mg Prana P3 Capsules
Bedtime: (30 min Prior)
30 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 120 mg+50 mg Raw
Week #5
Morning:
Frozen 0.5 ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (100 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
40 mg Prana P1 Capsules

Afternoon:
40 mg Prana P2 Capsules
Dinner:
40 mg Prana P3 Capsules
Bedtime: (30 min Prior)
40 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 160 mg+100 mg Raw
Week #6 (Advanced Holding Dose)
Morning:
Frozen 0.5 ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (100 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
50 mg Prana P1 Capsules
Afternoon:
50 mg Prana P2 Capsules
Dinner:
50 mg Prana P3 Capsules
Bedtime: (30 min Prior)
50 mg Prana P4 Capsules
Total Cannabinoids Absorbed Daily: 200 mg+100 mg Raw
Week #7-Week #12 (Advanced Stages)
Morning:
Frozen 0.5 ounce of proprietary blend of Fresh Frozen Raw *Cannabis* Juice (100 mg Raw) or Powdered Raw *Cannabis* Juice added to apple juice, super smoothie, or anti-inflammatory juice beverage.
100 mg Prana P1 Capsules
Afternoon:
100 mg Prana P2 Capsules
Dinner:
100 mg Prana P3 Capsules
Bedtime: (30 min Prior)
100 mg Prana P4 Capsules

Example 7: Exemplary Protocol for Anxiety/PTSD

Morning
5 mg-10 mg Prana P2 CBD AM Capsules (2:1 to 3:1, THC:CBD)
2 mg to 4 mg Prana P4 CBD:CBN Sublingual (1:1)
Afternoon:
2 mg to 4 mg Prana P4 CBD:CBN Sublingual (1:1)
Used when feeling anxiety or PSTD throughout the day.
After Dinner:
5 mg-10 mg Prana P3 CBD PM Capsules (2:1 to 1:1, THCa:CBDa)
4 mg Prana P4 CBD:CBN Sublingual (1:1)
Bedtime:
10 mg Prana P4 CBN Capsules

Example 8: Exemplary Protocol for Chronic Pain

Morning:
5 mg Prana P2 CBD AM Capsules (2:1 to 3:1, THC:CBD)
2 mg to 4 mg Prana P1 THCa Sublingual
Afternoon:
5 mg Prana P2 CBD AM Capsules (2:1 to 3:1, THC:CBD)
2 mg to 4 mg Prana P1 THCa Sublingual (As Needed)
Dinner:
10 mg Prana P3 CBD PM Capsules (2:1 to 1:1, THCa:CBDa)
2 mg to 4 mg Prana P1 THCa Sublingual
Bedtime:
10 mg Prana P4 CBN Capsules

Example 9: Exemplary Protocol for Opiate Dependency

Note: This is a 16 week program.
Week #1 & Week #2
Morning:
Prana P5-100 gms raw or 10 gms powder
5 mg Prana P1 Prana Capsule
2 mg Prana P2 CBD AM Sublingual (2:1 to 3:1, THC:CBD)
Afternoon:
5 mg Prana P1 Prana Capsule
2 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
5 mg Prana P1 Prana Capsule
2 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
10 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
2 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Daily: 31 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #3 & WEEK #4
Morning:
Prana P5-100 gms raw or 10 gms powder
10 mg Prana P1 Capsules
4 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
10 mg Prana P1 THCa Capsules
4 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
10 mg Prana P1 THCa Capsules
4 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
10 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
4 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 56 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #5 & WEEK #6
Morning:
Prana P5-100 gms raw or 10 gms powder
15 mg Prana P1 THCa Capsules
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
15 mg Prana P1 THCa Capsules
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
15 mg Prana P1 THCa Capsules
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
15 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
6 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 84 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #7 & WEEK #8
Morning:
Prana P5-100 gms raw or 10 gms powder
20 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
20 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
20 mg Prana P1 THC Capsules
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
20 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
6 mg Prana P4 Sublingual CBD:CBN (1:1)

Total Cannabinoids Absorbed Daily: 104 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #8 & WEEK #9
Morning:
Prana P5-100 gms raw or 10 gms powder
15 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
15 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
15 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
20 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
6 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 89 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #10 & WEEK #11
Morning:
Prana P5-100 gms raw or 10 gms powder
10 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
10 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
10 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
15 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
6 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 69 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #12 & WEEK #13
Morning:
Prana P5-100 gms raw or 10 gms powder
5 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Afternoon:
5 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Dinner:
5 mg Prana P1 Prana Capsule
6 mg Prana P2 CBD AM Sublingual (2:1 to 3:1)
Bedtime: (30 min Prior)
10 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
6 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 49 mg+50 mg Raw
Reduce Opiates by 10%-20%
Week #14 & WEEK #15
Morning:
Prana P5-100 gms raw or 10 gms powder
4 mg Prana P1 THCa Sublingual
5 mg Prana P2 CBD AM Capsule (2:1 to 3:1)
Afternoon:
4 mg Prana P1 THCa Sublingual
5 mg Prana P2 CBD AM Capsule (2:1 to 3:1)
Dinner:
4 mg Prana P1 THCa Sublingual
5 mg Prana P2 CBD AM Capsule (2:1 to 3:1)
Bedtime: (30 min Prior)
10 mg Prana P3 CBD PM Capsules (2:1 to 1:1)
4 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 41 mg+50 mg Raw
Opiates should be Reduced by 80-90%
Week #16+
Every 3rd Day+Prana P5-100 gms raw or 10 gms powder
Morning:
10 mg Prana P2 CBD AM Capsule (2:1 to 3:1)
4 mg Prana P1 THCa Sublingual (Only As Needed for Pain)
Afternoon:
4 mg Prana P1 THCa Sublingual (Only As Needed for Pain)
Dinner:
10 mg Prana P3 CBD PM Capsule (2:1 to 1:1)
4 mg Prana P1 THCa Sublingual (Only As Needed for Pain)
Bedtime: (30 min Prior)
4 mg Prana P4 Sublingual CBD:CBN (1:1)
Total Cannabinoids Absorbed Daily: 36 mg+25 mg Raw
Opiates should be Reduced by 90%-100%.

Other Embodiments

While the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

What is claimed is:

1. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is tetrahydrocannabinolic acid (THCa).

2. The formulation of claim **1**, further comprising at least one terpene/flavonoid.

3. The formulation of claim **2**, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

4. The formulation of claim **2**, wherein the formulation comprises no more than 4% terpene.

5. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is tetrahydrocannabinol (THC).

6. The formulation-of claim **5**, further comprising at least one terpene/flavonoid.

7. The formulation of claim **5**, wherein the formulation comprises no more than 4% terpene.

8. The formulation of claim **6**, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

9. The formulation of claim **1** or **5**, wherein the formulation comprises no more than 4% terpene, wherein said terpene comprises myrcene, caryophyllene, and limonene.

10. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is cannabidiol (CBD).

11. The formulation of claim **10**, wherein the formulation further comprises less than 1% THC.

12. The formulation-of claim **10**, further comprising at least one terpene/flavonoid.

13. The formulation of claim **10**, wherein the formulation comprises no more than 4% terpene.

14. The formulation of claim **12**, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

15. The formulation of claim 10, wherein the formulation comprises no more than 4% terpene, wherein said terpene comprises myrcene, caryophyllene, and limonene.

16. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is THCa and cannabidiolic acid (CBDa).

17. The formulation-of claim 16, further comprising at least one terpene/flavonoid.

18. The formulation of claim 16, wherein the formulation comprises no more than 4% terpene.

19. The formulation of claim 17, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

20. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids are THC and CBD.

21. The formulation-of claim 20, further comprising at least one terpene/flavonoid.

22. The formulation of claim 20, wherein the formulation comprises no more than 4% terpene.

23. The formulation of claim 21, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

24. The formulation of claim 16 or 20, wherein the formulation comprises no more than 4% terpene, wherein said terpene comprises myrcene, limonene, pinene, and caryophyllene.

25. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids are CBD, cannabinol (CBN) and THC.

26. The formulation of claim 25, wherein the formulation comprises less than 9% THC.

27. The formulation-of claim 25, further comprising at least one terpene/flavonoid.

28. The formulation of claim 25, wherein the formulation comprises no more than 4% terpene.

29. The formulation of claim 27, wherein the terpene/flavonoid is d-limonene linalool, 1,8-cineole (eucalyptol), α-pinene, terpineol-4-ol, p-cymene, borneol, Δ-3-carene, β-sitosterol, β-myrcene, β-caryophyllene, cannflavin A, apigenin, quercetin or pulegone.

30. The formulation of claim 25, wherein the formulation comprises no more than 4% terpene, wherein said terpene comprises myrcene, pinene and caryophyllene.

31. The formulation of any one of the proceeding claims, wherein the formulation is infused in a medium chain triglyceride (MCT).

32. The formulation of claim 31, wherein the MCT is NEOBEE 895.

33. The formulation of claim 1, 5, 10, 16, 20, or 25, formulated for oral, sublingual, buccal, or topical administration.

34. The formulation of claim 33, wherein the sublingual formulation further comprises a sweetener.

35. The formulation of claim 34, wherein the sweetener is a *stevia* extract.

36. The formulation of claim 34, further comprising lemon oil, orange oil or both.

* * * * *

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 22-1363

Short Case Caption: United Cannabis Corporation v. Pure Hemp Collective Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 6,342 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 03/14/2022

Signature: /s/ James R. Gourley

Name: James R. Gourley

Save for Filing